NAHRI

National Association of Healthcare Revenue Integrity

# Professional Advocacy Committee

POSITION PAPER

The National Association of Healthcare Revenue Integrity (NAHRI) Professional Advocacy Committee is responsible for the research and development of position papers that can help further the revenue integrity profession and bring awareness to matters impacting revenue integrity practices.

Committee members include:

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## Submitting Comments to Medicare on Its FY 2020 IPPS Proposed Rule

### I. Title: Medicare Inpatient CAR-T Cell Therapy Reimbursement for FY 2020

Inpatient hospital reimbursement for CAR-T is woefully inadequate and must be addressed for FY 2020 so that hospitals can continue providing this important therapy to the patients who need it. Hospital transplant program directors, clinicians, and finance administrators (CFO, CEO, etc.) must advocate for improved reimbursement ASAP.

### II. Authors


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### III. Introduction

On April 23, 2019, CMS released the FY 2020 inpatient prospective payment system (IPPS) proposed rule. Providers, patient advocates, and professional organizations focused on cell and gene therapies, specifically on Chimeric Antigen Receptor T-cell (CAR-T) therapy, have been awaiting the release of the rule, hoping that CMS would provide a reimbursement solution. Current reimbursement consists of the MS-DRG 016 payment, the new technology add-on payment (NTAP) capped at $186,500, and potential for outlier payment. This has left hospitals facing large financial losses. CMS proposed a few changes for FY 2020, specifically one change to the NTAP calculation. However, even if all of CMS' proposed changes are finalized, the positive financial impact to most hospitals is likely to be minimal and certainly not enough to offset the types of case losses being experienced today. The NAHRI Professional Advocacy Committee is addressing the CAR-T reimbursement issue because we want to ensure that CMS understands the continued detrimental impact of insufficient inpatient reimbursement on providers and patients looking to access this important treatment.

### IV. Narrative

When considering what regulatory changes CMS is proposing, and thus, changes that are most likely to be finalized, it is necessary to hone in on the language used in the proposed rule. For example, if CMS says, “we propose” then it means CMS

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is issuing a concrete proposal and is looking for input. For CAR-T, CMS proposed continuing to assign all CAR-T cases to MS-DRG 016 since they do not feel they have enough case volume to create a new DRG for CAR-T yet; while some may not like this or question it, it is indeed in line with CMS' normal process.

A proposal that would impact the calculation of all NTAP payments could also have an effect on CAR-T. CMS proposed changing the current NTAP payment cap of 50% of the cost of the new drug/technology to 65%. CMS also proposed keeping the NTAP in place for another year for CAR-T. Keeping the NTAP in place for another year was an expected proposal, but the NTAP formula change was not. It is, however, CMS' attempt to address the provider community's concerns about the problems with the NTAP calculation and the large payment shortfall associated with CAR-T. On first glance, the proposal of 50% to 65% appears to be substantial, but upon closer look—and by that we mean when hospitals run their numbers based on their current charging practices and CMS' proposed change—this proposal is likely to result in a small improvement but nowhere near enough of a payment fix to eradicate the substantial difference between treatment costs and expected payment. This is because CMS' proposal to increase the NTAP formula to 65% is still in the context of there being a cap, which means all that CMS has proposed is moving the maximum NTAP a hospital can earn as a result of its billed charges from $186,500 to $242,500. In this way, there will still be a need for providers to set their charges in a manner that factors in CMS' formula and will still result in significant losses on just the CAR-T product cost, let alone patient care costs. Hospitals must remember that the current formula, along with CMS' proposal, still requires a calculation that takes the total covered billed charges and reduces them to cost using the hospital's overall cost-to-charge ratio (CCR), subtracts out the MS-DRG payment, and then pays the lesser of the residual calculated cost which today is set at 50% and for FY 2020 proposed to be set at 65% or the NTAP cap. For providers whose charging practices do not reflect an appropriate mark-up for the product (i.e., the acquisition cost divided by their hospital's CCR as the price for the product, the computed NTAP amount will be far less than the cap. And this will not change substantially even if the cap is set at 65% rather than 50%. This proposal also does not provide a long-term solution to the inpatient payment issue for CAR-T since NTAP is only in place for two or three years.

**"Although CMS did not propose creating a new CAR-T MS-DRG for FY 2020, the agency knows it will likely have to in FY 2021 or 2022. For this reason, CMS asked for quite a bit of input on how to best create the MS-DRG."**

The words CMS uses are important because few proposals were made. It may not appear as such because CMS also asks for lots of input by way of requesting comments on many issues, including whether the NTAP payment should be made uniformly at 65% for CAR-T. If this proposal were finalized, all PPS providers would receive the full amount of the new cap or $242,450, which removes the cap or the "lesser of" language portion of the calculation. If CMS were to finalize this at the 65% level, or better yet at 80% or 100%, then it would be a huge improvement over its current proposals. Since CMS raised the possibility of considering something other than 65% for the NTAP payment, it would behoove providers to weigh in on why a different, higher number would be appropriate.

Additionally, although CMS did not propose creating a new CAR-T MS-DRG for FY 2020, the agency knows it will likely have to in FY 2021 or 2022. For this



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reason, CMS asked for quite a bit of input on how best to create the MS-DRG and how adjustments to the relative weight should work. In light of concerns around CAR-T reimbursement, CMS is looking for input on if a new MS-DRG for CAR-T were created in the future where the vast majority of the payment rate for this product would be subject to the wage-index, indirect medical education, and disproportionate share adjustments, and how these adjustments might impact the overall payment and whether that is appropriate. Again, providers should weigh in now as this will impact what they will get paid in the future.

Finally, CMS raised its desire to receive comments about possible payment alternatives for CAR-T therapy, how it might think differently about how it reimburses these therapies, and the impact of the implementation timing on providers and Medicare beneficiaries.

**"We encourage you to comment on the proposed rule and share your experience with CAR-T reimbursement."**

**V. Actions**

Two features of CMS' proposals and discussion of CAR-T therapy reimbursement are notable for providers and revenue integrity professionals. First, CMS acknowledged that providers have real, ongoing problems with inpatient CAR-T therapy reimbursement and that some sort of a solution is needed. Second, CMS needs more information, ideas, and details in order to pursue a solution. Provider organizations that are treating CAR-T patients and dealing with the consequences of inadequate reimbursement are best suited to relay feedback to CMS. We cannot forget that everything happening at the agency right now is in the context of the administration's larger focus on drug pricing issues. At times, it may feel like we are pushing water up a hill. But if we do not advocate for the changes we need then we cannot make the progress we desire.

Specific, data-driven provider comments are critical. Let CMS know about the challenges you are facing in terms of financial impact, patient access, and operational issues. Your comments can absolutely shape regulatory policy. Unless provider organizations comment about their experiences and challenges, CMS could end up making decisions in a vacuum.

We encourage you to comment on the proposed rule and share your experience with CAR-T reimbursement, particularly the NTAP payments you receive. Consider getting in touch with other providers or health systems. Reach out to professional associations in your State like the American Hospital Association as well as national organizations such as, the American Society of Transplantation and Cellular Therapy, the American Society of Hematology, the Healthcare Financial Management Association, and others etc., to understand their perspectives.

It may be tempting to use a form letter or template or to repeat language written in another organization's letter that resonates with your experience. However, we strongly encourage you address CMS in your own words, adding as many specific details (no PHI) as you can. The unique facets of your experience will be the most compelling and meaningful to CMS, and far more important than a simple reiteration of support for the points others are making.



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We also encourage you to think broadly about the operational impact the proposed rule may have on your organization. Expressing these concerns in addition to your reimbursement issues will help the agency see how difficult it is to provide this breakthrough therapy and it might help give insight how the agency needs to come up with alternative payment solutions for CAR-T; as well as future cell and gene therapies, and the impact of the implementation timing on providers and Medicare beneficiaries. This is a place that providers may wish to comment that CAR-T showcases how the disparate inpatient and outpatient payment systems that result in dramatically different payment rates no longer make sense with how hospital care is delivered and result in vastly different financial incentives based on site of care. Providers should weigh in on how a new payment model could mitigate some of these concerning realities.

Comments are due on June 24, 2019, by 5 p.m. Eastern Daily Time. Comments can be submitted electronically through *regulations.gov* at *www.regulations.gov/document?D=CMS-2019-0073-0003*, or via mail at:

**Department of Health and Human Services,**
**Attention: CMS-1716-P,**
**P.O. Box 8013,**
**Baltimore, MD 21244-1850.**

Please allow sufficient time for mailed comments to be received before the close of the comment period.

**VI. Resources**

FY 2020 Inpatient Prospective Payment System Proposed Rule was published in the Federal Register on May 3rd, 2019: *www.federalregister.gov/documents/2019/05/03/2019-08330/medicare-program-hospital-inpatient-prospective-payment-systems-for-acute-care-hospitals-and-the*



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